

REMARKS/ARGUMENTS

Claims 1-48 are pending in the present application. Claims 32-34 and 37-48 have been withdrawn from consideration by the Examiner. Claims 1, 8 and 35 have been amended herein. Claims 1 and 35 have been amended to recite that the solution of TCPD comprises the TCPD pre-dissolved in basified alcohol. Claim 1 has also been amended to provide proper antecedent basis. Claim 8 has been amended in view of the fact that some of its original language is now included in independent Claim 1 from which Claim 8 depends. Support for these amendments may be found in the application as filed, notably in the Specification at page 8, line 12 through page 9, line 4, as well as in original Claim 8. No new matter has been introduced by these amendments.

Applicant respectfully requests reconsideration of the rejections of record in view of the foregoing amendments and the following remarks.

The Claims Satisfy the Requirements of 35 U.S.C. § 112, Second Paragraph

Claims 1-31 and 35-36 have been rejected under 35 U.S.C. § 112, second paragraph, as being allegedly vague and indefinite with respect to the phrase “dysplastic or carcinomic.” Applicant respectfully traverses this rejection.

The proper inquiry when determining whether a claim satisfies the requirements of 35 U.S.C. § 112, second paragraph, is a determination “whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics Inc. v. Safety Travel Chairs, Inc.*, 1 U.S.P.Q. 2d 1081, 1088 (Fed. Cir. 1986). Thus, if those skilled in the art can understand what is claimed when the claim is read in light of the specification, a rejection under 35 U.S.C. § 112, second paragraph is improper.

Alternative expressions are permitted in patent claims if they present no uncertainty or ambiguity with respect to the scope or clarity of the claims. (MPEP 2173.05(h)) Alternative expressions using “or” are acceptable under 35 U.S.C. 112. *See In re Gaubert*, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975); (MPEP 2173.05(h)).

The Examiner has provided no explanation of why the alternative phrase “dysplastic or carcinomic” would not be understood by a skilled artisan in light of the specification. Applicant asserts that the claims clearly convey the metes and bounds of the invention when

read in light of the specification. Accordingly, Applicant requests reconsideration and withdrawal of the rejection.

The Claims As Amended Are Drawn to Novel Subject Matter

Claims 1, 2, 5-7, 10, 14-16, 20-28, 30, 31 and 35-36 stand rejected under 35 U.S.C. §102(e) as allegedly anticipated by Adair et al. (U.S. Pat. No. 6,316,215). Applicant respectfully traverses this rejection as applied to the present claims as amended herein.

Proof of anticipation (i.e. prior knowledge by others) requires that all of the elements and limitations of the claimed subject matter must be described, expressly or inherently, in a single prior art reference. *See In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988). The single reference must not only describe, but must enable the claimed invention, including all claim limitations, with such clarity and detail as to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. *See Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

With respect to the alleged anticipation by Adair et al., Adair et al. briefly notes that one of several photosensitive compounds to which cells may be exposed is TCPP. No conditions are provided for preparation of any TCPP-containing solution; nor are any conditions provided for exposure of cells to TCPP. One of ordinary skill in the art would not be able to discern from the disclosure of Adair teaching sufficient to enable practice of a method of treating cells with TCPP without undue experimentation. Thus, the disclosure of Adair et al. fails to provide disclosure sufficient to enable a skilled artisan to use TCPP as alleged by the Examiner, and thus fails to anticipate the present claims.

In addition, Adair et al. fails to disclose any method involving a solution of TCPP which comprises the TCPP pre-dissolved in basified alcohol. As explained *supra*, independent claims 1 and 35 have been amended herein to recite that the solution of TCPP comprises the TCPP pre-dissolved in basified alcohol. In view of the foregoing, Applicant submits that Adair et al. fails to anticipate the present claims, and therefore requests withdrawal of the rejection under 35 U.S.C. §102(e) on the basis of Adair et al.

Claims 1-3, 5-7, 14-16, 30, 31, and 35-36 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by Cole et al. (U.S. Pat. No. 5,391,547). Applicant respectfully traverses this rejection as applied to the present claims as amended herein.

As explained *supra*, independent claims 1 and 35 have been amended herein to recite that the solution of TCPP comprises the TCPP pre-dissolved in basified alcohol. Cole et al. fails to disclose the use of a solution of TCPP which comprises the TCPP pre-dissolved in basified alcohol. Therefore, Cole et al. fails to anticipate the present claims. Applicant thus respectfully requests withdrawal of the rejection under 35 U.S.C. §102(b) on the basis of Cole et al.

The Claims As Amended Are Drawn to Non-obvious Subject Matter

Claims 1-31 and 35-36 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious over Adair et al. The Examiner acknowledges that Adair et al. fail to teach “that the cells are fixed, TCPP is pre-dissolved at a particular pH, TCPP being at a particular concentration and TCPP contacted at a particular time and temperature and the percentage of cells that are TCPP bound.” (Office Action at page 5). The Examiner alleges, however, that arriving at these aspects of the claimed invention would be have been a matter of routine optimization for the skilled artisan, therefore they are alleged to be obvious. Applicant respectfully traverses this rejection.

When applying 35 U.S.C. 103, the U.S. Patent and Trademark Office must adhere to the following:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of any combination;
- (C) The references must be viewed without the benefit of impermissible hindsight afforded by the claimed invention; and
- (D) Reasonable expectation of success is the standard with which obviousness is determined. (*See* MPEP 2141).

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 180 USPQ 580

(CCPA 1974). (MPEP 2143.03). A *prima facie* case of obviousness also requires that the prior art suggest the desirability of the claimed invention. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *See In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432. (MPEP 2143.01).

The claims, as amended herein, recite the use of a solution of TCPP which comprises the TCPP pre-dissolved in basified alcohol. As discussed *supra*, Adair et al. fails to teach the use of TCPP dissolved in basified alcohol. Further, there is no suggestion or motivation in the cited reference to modify the teaching of the reference to arrive at the invention as presently claimed. The use of TCPP dissolved in basified alcohol is more than "routine optimization," as suggested by the examiner. As stated in the specification (e.g., at page 10, lines 4-11) the improved method for solubilizing TCPP preserves its activity to a greater extent than accomplished by other methods, and contributes to the efficiency of the method (less time for the assay, lower concentrations of TCPP needed). There is no disclosure in Adair et al. that even hints that dissolving TCPP in basified alcohol would be advantageous. Since the reference fails to supply the motivation even to achieve the invention as claimed, clearly the reference also fails to supply any expectation of success in practicing the claimed invention.

In view of the foregoing, Applicant submits that the cited reference fails to establish a *prima facie* case of obviousness. Withdrawal of this rejection is therefore requested.

Claims 1-31 and 35-36 stand rejected under 35 U.S.C. §103(a) as being allegedly obvious over Cole et al.

The claims, as amended herein, recite the use of a solution of TCPP which comprises the TCPP pre-dissolved in basified alcohol. As discussed *supra*, Cole et al. fails to teach or suggest the use of TCPP dissolved in basified alcohol and the advantage of the solubilization method, and thus fails to teach or suggest all of the limitations of the claimed method. In addition, Cole et al. teaches away from the claimed method. Cole et al. discloses incubation of cells with TCPP for either 6 or 24 hours. (*See* Cole et al. at Col. 5, lines 36-50). It notes that when a 6-hour incubation was used, washing of the cells with PBS caused the

fluorescence to diminish, thus suggesting that the “porphyrin was not firmly bonded or internalized into the cells.” (*Id.* at Col. 5, lines 43-43). In contrast, incubation for 24 hours maximized TCPP localization in the cells. (*See id.* at Col. 6, lines 38-40). Therefore, given the disclosure of Cole et al., one of skill in the art would conclude that relatively long incubation times up to 24 hours are required to optimize staining with TCPP. Cole et al. does not provide any motivation to reduce incubation times, since increasing incubation times from 6 to 24 hours improved results. Cole et al. therefore does not provide any expectation of success for a method using shorter incubation times. The method of the present claims, however, works well with short incubation times, ranging from 0.2 minutes to 2 hours. (*See* Specification at page 7, line 15). Cole et al. therefore fails to teach or suggest the present claims, and in fact, teaches away from the present claims. Since the reference fails to supply the motivation even to achieve the invention as claimed, clearly the reference also fails to supply any expectation of success in practicing the claimed invention.

In view of the foregoing, Applicant submits that the cited reference fails to establish a *prima facie* case of obviousness. Withdrawal of this rejection is therefore respectfully requested.

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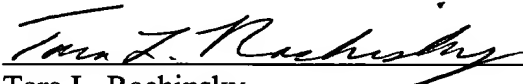
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Conclusion

In view of the foregoing, Applicant believes that, upon entry of this amendment, all claims now pending in this application are in condition for allowance. An early notification to that effect is respectfully requested.

Respectfully submitted,

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